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RPTO/SB/21 (08-00)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	1

Application Number	09/936,957
Filing Date	09/17/2001
First Named Inventor	Meikle
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	021385-014010US

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Response
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  1) **Twenty (20) cited references**
  2) **Return receipt postcard**

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.
Total number of pages does not include cited references.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Joe Liebeschuetz Reg No. 37,505
Signature	
Date	June 5, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: June 5, 2002

Typed or printed name	Chris Fitting		
Signature		Date	June 5, 2002

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PA 3227623 v1

PATENT
Attorney Dock[redacted]lo.: 021385-014010US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Meikle et al.

Application No.: 09/936,957

Filed: September 17, 2001

For: DIAGNOSIS OF LYSOMAL STORAGE DISORDERS USING SAPOSINS AND OTHER MARKERS

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

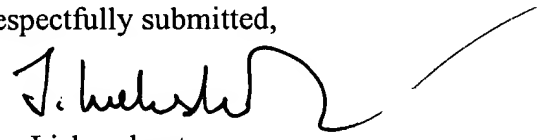
Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Joe Liebeschuetz
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	09/936,957
Filing Date	September 17, 2001
First Named Inventor	Meikle
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	021385-014010US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	U.S. Patent Document Number	U.S. Patent Document Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	5,501,957		Dennis et al.	03-26-1996	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Foreign Patent Document Number[4]	Foreign Patent Document Kind Code[5] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

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Application Number	09/936,957
Filing Date	September 17, 2001
First Named Inventor	Meikle
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	021385-014010US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AB	AERTS et al., "The occurrence of two immunologically distinguishable β-glucocerebrosidases in human spleen," Eur. J. Biochem., 150:565-574 (1985).	
	AC	BAGHDIGUIAN et al., "Co-localization of suramin and serum albumin in lysosomes of suramin-treated human colon cancer cells," Cancer Letters, 101:179-184 (1996).	
	AD	BURKHARDT et al., "The Giant Organelles in *Beige* and Chediak-Higashi Fibroblasts Are Derived from Late Endosomes and Mature Lysosomes," J. Exp. Med., 178:1845-1856 (1993).	
	AE	CHAMBERLAIN et al., "Generation and Characterization of Monoclonal Antibodies to Human Type-5 Tartrate-Resistant Acid Phosphatase: Development of a Specific Immunoassay of the Isoenzyme in Serum," Clin. Chem., 41(10):1495-1499 (1995).	
	AF	COLMAN, P., "Effects of amino acid sequence changes on antibody-antigen interactions," Reserch In Immunology, 145:33-36 (1994).	
	AG	CONARY et al., "Synthesis and Stability of Steriod Sulfatase in Fibroblasts from Multiple Sulfatase Deficiency," Biological Chemistry, 369:297-302 (1988).	
	AH	DAHLGREN et al., "The lysosomal membrane glycoproteins Lamp-1 and Lamp-2 are present in mobilizable organelles, but are absent from the azurophil granules of human neutrophils," J. Biochem., 311:667-674 (1995).	
	AI	KARAGEORGOS et al., "Lysosomal Biogenesis in Lysosomal Storage Disorders," Experimental Cell Research, 234:85-97 (1997).	
	AJ	KISHIMOTO et al., "Saposins: structure, function, distribution, and molecular genetics," J. Lipid Research, 33:1255-1267 (1992).	
	AK	MEIKLE et al., "Diagnosis of lysosomal storage disorders: evaluation of lysosome-associated membrane protein LAMP-1 as a diagnostic marker," Clinical Chemistry, 43(8):1325-1335 (1997).	
	AL	MICHELAKAKIS et al., "Characterization of glucocerebrosidase in Greek Gaucher disease patients: mutation analysis and biochemical studies," J. Inher. Metab. Dis., 18:609-615 (1995), with abstract	
	AM	PASCHKE et al., "Infantile type of sialic acid storage disease with sialuria," Clinical Genetics, 29:417-424 (1986).	
	AN	RENLUND, M., "Clinical and laboratory diagnosis of Salla disease in infancy and childhood," Journal of Pediatrics, 104(2):232-236 (1979).	
	AO	RENLUND et al.., "Increased Urinary Excretion of Free *N*-Acetylneuraminic Acid in Thirteen Patients with Salla Disease," European Journal of Biochemistry, 101:245-250 (1979).	
	AP	RENLUND et al., "Salla disease: A new lysosomal storage disorder with disturbed sialic acid metabolism," Neurology, 33:57-66 (1983).	

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 3

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Filing Date	September 17, 2001
First Named Inventor	Meikle
Group Art Unit	Unassigned
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Attorney Docket Number	021385-014010US

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	AQ	RENLUND et al, "Studies on the Defect Underlying the Lysosomal Storage of Sialic Acid in Salia Disease: Lysosomal Accumulation of Sialic Acid Formed From *N*-Acetyl-Mannosamine or Derived from Low Density Lipoprotein in Cultured Mutant Fibroblasts," Journal of Clinical Investigation, 77:568-574 (1986).	
	AR	RODRIGUEZ-SERNA et al., "Angiokeratoma Corporis Diffusum Associated With β-Mannosidase Deficiency," Arch. Dermatol., 132:1219-1222 (1996).	
	AS	SANDOVAL et al., "Lysosomal Integral Membrane Glycoproteins Are Expressed at high Levels in the Inclusion Bodies of I-Cell Disease Fibroblasts," Arch. Biochem. & Biophysics 271(1):157-167 (1989).	
	AT	WAHEED et al., "Enhanced Breakdown of Arylsulfatase A in Multiple Sulfatase Deficiency," European Journal of Biochemistry, 123:317-321 (1982).	

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